

ASX:NRT
NASDAQ:NVGN

Novogen Ltd
(Company)

ABN 37 063 259 754

Capital Structure

Ordinary Shares on
issue:

429 M

Board of Directors

Mr John O'Connor
Chairman
Non-Executive Director

Mr Bryce Carmine
Deputy Chairman
Non-Executive Director

Dr James Garner
Chief Executive Officer
Managing Director

Mr Ian Phillips MNZM
Non-Executive Director

Mr Iain Ross
Non-Executive Director

Mr Steven Coffey
Non-Executive Director

MARKET RELEASE

12 September 2016

US FDA APPROVES INVESTIGATIONAL NEW DRUG (IND) APPLICATION FOR CANTRIXIL™ (TRX-E-002-1) IN OVARIAN CANCER

- **Cantrixil (TRX-E-002-1) is Novogen's lead development candidate, and is being developed as an intraperitoneal therapy for patients with ovarian cancer**
- **Investigational New Drug (IND) application is the key regulatory filing to initiate clinical trials in the United States**
- **First-in-human (FIH) phase I study remains on track for initiation in 4Q 2016, as per previous guidance**

Sydney, 12th September 2016 – Australian oncology-focused biotechnology company Novogen Ltd (ASX: NRT; NASDAQ: NVGN) today announced that it had received confirmation from the United States Food and Drug Administration (FDA) that the Investigational New Drug (IND) application for Cantrixil (TRX-E-002-1) had been successfully opened, and the phase I study of Cantrixil in patients with ovarian cancer may therefore proceed as planned.

Dr James Garner, CEO of Novogen, commented “we are grateful to the FDA for their thorough and comprehensive review of our submission, and we are pleased to have their approval to move forward with the study. The team is already working alongside Quintiles, our contract research organisation, to make the necessary submissions to human research ethics committees at each of the participating sites, and we continue to anticipate initiation of the phase I study in the fourth quarter of 2016, as previously indicated.”

[ENDS]

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About the Cantrixil (TRXE-E-002-1) development candidate

Cantrixil is a cyclodextrin-based formulation of the active ingredient, TRX-E-002-1, which has shown *in vitro* and *in vivo* anti-cancer activity in a range of tumour types. The Company anticipates that, if approved, the drug product would be used as an intra-peritoneal chemotherapy, either alone or in combination with other agents, and in one or more cancers of the abdominal or pelvic cavity (e.g. ovarian, uterine, colorectal or gastric carcinomas). A first-in-human clinical study is planned to commence in the fourth quarter of 2016.

About Novogen Limited

Novogen Limited (ASX: NRT; NASDAQ: NVGN) is an oncology-focused biotechnology company based in Sydney, Australia. Novogen has two proprietary drug discovery platforms (superbenzopyrans and anti-tropomyosins) with the potential to yield first-in-class agents across a range of oncology indications. The three lead molecules Cantrixil, Anisina, and Trilexium are in preclinical development, with the most advanced molecule, Cantrixil, slated to enter clinical trials in late 2016. For more information, please visit: www.novogen.com